



15 minutes-
total

A Software Assistant to Facilitate Guideline Development

GIN Annual Meeting 2011

Richard N. Shiffman, MD, MCIS

Yale School of Medicine
New Haven, Connecticut, USA

Overview

- **Essential background**
 - Rationale: Why software?
 - Ideal recommendation
 - Action-types
 - Level of obligation
- **Building a recommendation**

Rationale

- Key Action Statements (“recommendations”) differentiate guidelines from other publications
 - What to DO!
- Shortcomings lead to difficulties in implementation
 - Often vague, underspecified, ambiguous
 - Unclear linkage of recommendation to supporting evidence
 - Expected level of adherence not explicit
- Many panel members are unfamiliar with recommendation building
- BRIDGE-Wiz program offers a systematic and replicable approach



**CLINICAL PRACTICE
GUIDELINES
WE CAN TRUST**

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Establishing Evidence Foundations for and Rating Strength of Recommendations

5.1 For each recommendation, the following should be provided:

- An explanation of the reasoning underlying the recommendation, including:
 - A clear description of potential benefits and harms.
 - A summary of relevant available evidence (and evidentiary gaps), description of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence.
 - An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation.
- A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation.
- A rating of the strength of the recommendation in light of the preceding bullets.
- A description and explanation of any differences of opinion regarding the recommendation.

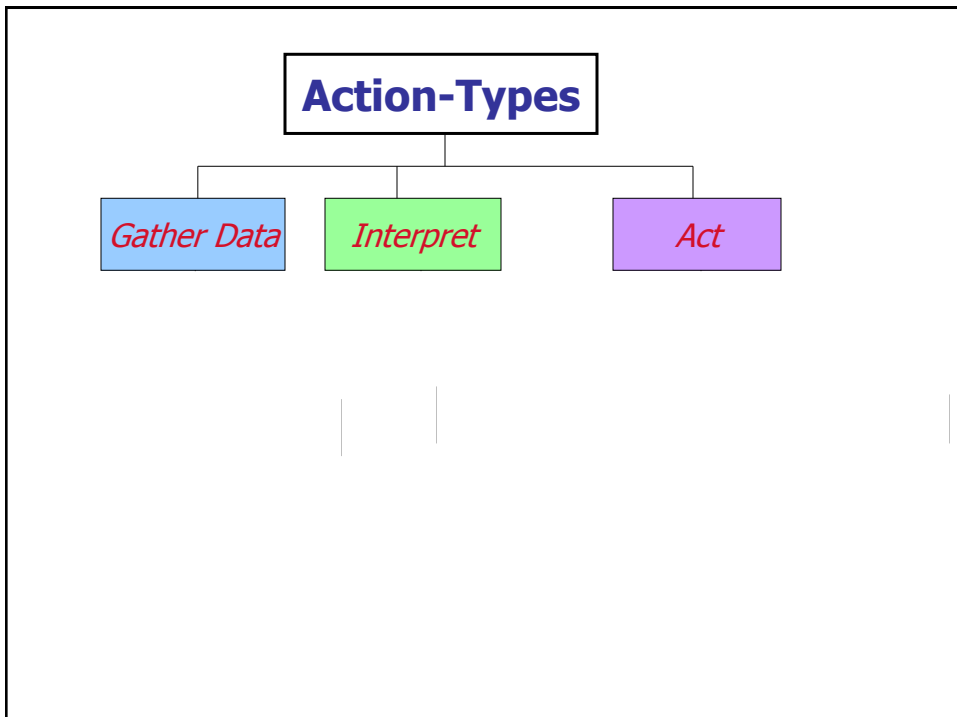
Articulation of Recommendations

6.1 Recommendations should be articulated in a standardized form detailing precisely what the recommended action is, and under what circumstances it should be performed.

6.2 Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated.

Authors Should Be Explicit About

- **WHEN** {under what circumstances} **Denominator**
- **WHO** {in the Intended Audience} -----
- **Ought to** {with what level of obligation} **Numerator**
- **DO WHAT**
- {To **WHOM**} {which members of the target population} -----
- **HOW**
- **WHY**



Statement of Fact vs Recommendation

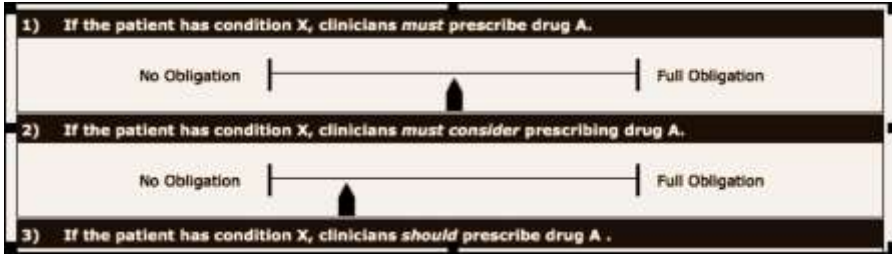
- Anticholinergic agents are appropriate and effective treatment alternatives for the management of lower urinary tract symptoms secondary to benign prostatic hypertrophy (BPH)
- Urologists may prescribe anticholinergic agents for management of lower urinary tract symptoms secondary to BPH if the patient does not have an elevated post-void residual AND the lower urinary tract symptoms are predominantly irritative.

An Implementable Recommendation...

- Members of the intended audience execute the recommended action in a consistent way.
- Members of the intended audience agree when the recommendation should be applied.
- The recommendation is identifiable as such and its discussion is concise.
- Adherence to the recommendation is measurable.
- Outcomes of following the recommendation are measurable.
- Justification for the recommendation is stated explicitly.
- Quality of supporting evidence and recommendation strength are indicated.
- Patient or practice considerations that require individualization are specified.

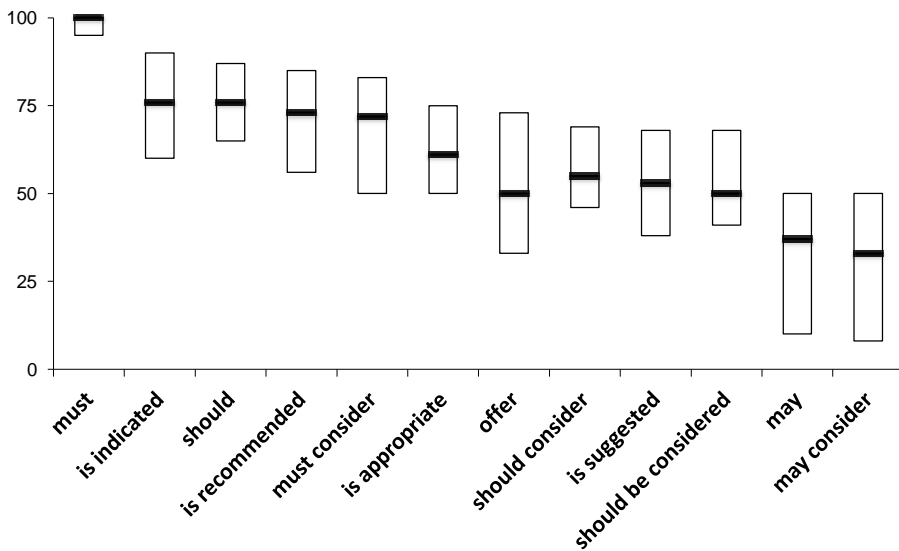
How “Should” We Write Guideline Recommendations

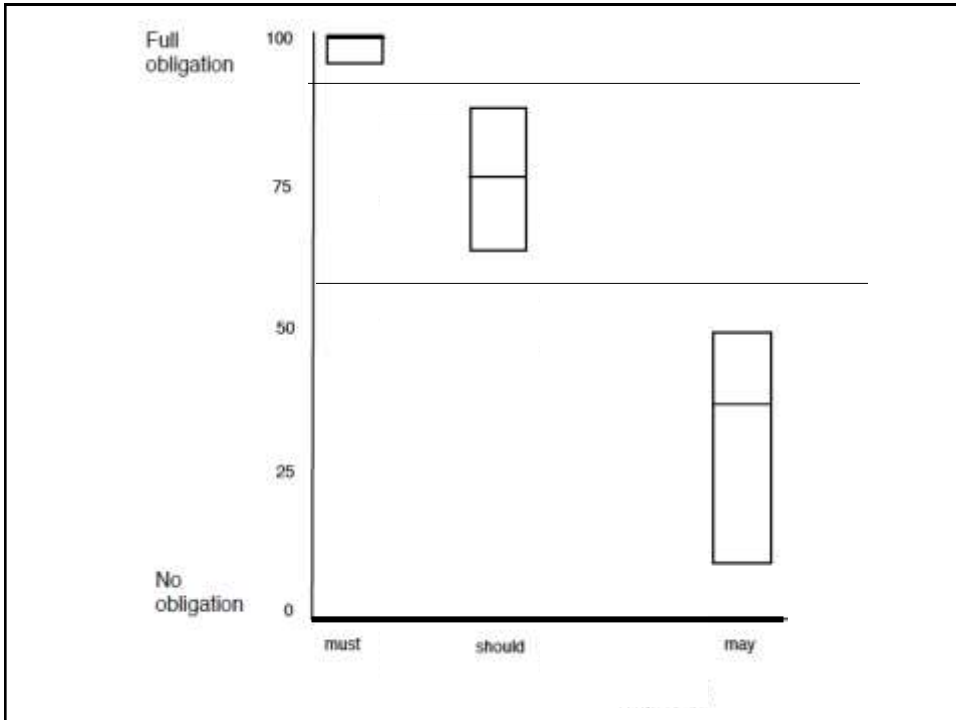
- Web-based survey of 1332 registrants to AHRQ Annual Meeting
- Presented 12 statements:



- Participants indicated the level of obligation they believed guideline authors intended using a slider from No obligation to Full obligation (0 to 100)

Level of Obligation





Bridge the Gap Between Authors and Implementers With BRIDGE-Wiz

([Building Recommendations In a Developer's Guideline Editor](#))

Kids with newly diagnosed type 2 diabetes should be started on metformin as first-line treatment along with diet and exercise.

Complete COGS Checklist or Create a Recommendation

Welcome

Welcome to Bridgewiz

BridgeWiz aims to assist guideline authors to write more comprehensive guidelines and clearer, more actionable recommendations. BridgeWiz incorporates a number of features that are designed to safeguard against creating vague and underspecified recommendations.

The end-products of BridgeWiz include:

- A completed template that provides information required to be compliant with a guideline quality checklist, the COGS appraisal
- One or more skeleton IF-THEN statements that are expected to facilitate implementation in a computer-based decision support system
- A partially populated Evidence Profile for each Key Action Statement.

Begin by selecting an activity described below:

Create COGS Statement

Create Key Action Statement

Notes

Guideline Quality Appraisal	
Focus:	Describe the primary clinical condition and intervention or user technology that the guideline addresses; indicate any alternative preventive, diagnostic or therapeutic interventions that were considered during development.
Goal:	Describe the goal that following the guideline is expected to achieve, including the rationale for development of a guideline on this topic.
Users/Setting:	Describe the intended users of the guideline (e.g., providers, patients) and the settings in which the guideline is intended to be used.
Target population:	Describe the patient population eligible for guideline recommendations and list any exclusion criteria.
Developer:	Identify the organization(s) responsible for guideline development and the names/positions/roles/conflict of interest of individuals involved in the guideline's development.
Funding source/sponsor:	Identify the funding source(s) and describe its role in developing and/or updating the guideline. Declare potential conflict of interest.
Source of Funding:	
Conflict Of Interest:	
Evidence collection:	Describe the methods used to search the scientific literature, including the range of dates and databases searched, and criteria applied to filter the retrieved evidence.

Choose Action-Type

RULE EDITOR

What

What type of activity do you propose? NDT

Definition

Notes

Action-Types

What

What type of activity do you propose?

NOT

- GATHER DATA
- INQUIRE
- EXAMINE
- TEST
- MONITOR
- DRAW CONCLUSION
- CONCLUDE
- ACTIVITY
- ADVOCATE
- DISPOSE
- DOCUMENT
- EDUCATE/COUNSEL
- PERFORM
- PREPARE
- PRESCRIBE
- PREVENT
- REFER/CONSULT

What

What type of activity do you propose? NOT

Based on the PRESCRIBE action type,
select a verb:

What

What type of activity do you propose? NOT

Based on the PRESCRIBE action type, select a verb:

- reduce
- repeat
- replace
- reserve
- restart
- review
- start
- suggest
- supplement
- taper
- titrate
- treat
- use
- utilize
- warrant

“Start” WHAT?

What

What type of activity do you propose? NOT

Based on the PRESCRIBE action type, select a verb:

Start what?

VERB	WHAT
start	

What

What type of activity do you propose? NOT

Based on the PRESCRIBE action type, select a verb:

Start what?

VERB	WHAT	
start	metformin as first-line treatment	<input type="button" value="AND"/> <input type="button" value="OR"/> <input type="button" value="DEL"/>

Another Action

What

What type of activity do you propose?

VERB	WHAT	
start	metformin as first-line treatment	<input type="button" value="AND"/> <input type="button" value="OR"/> <input type="button" value="DEL"/>
AND		<input type="button" value="AND"/> <input type="button" value="OR"/> <input type="button" value="DEL"/>

Add Another Action

What

What type of activity do you propose? EDUCATE/COUNSEL NOT

Based on the EDUCATE/COUNSEL action type, recommend

select a verb:

Recommend what?

	VERB	WHAT			
	start	metformin as first-line treatment	<input type="button" value="AND"/>	<input type="button" value="OR"/>	<input type="button" value="DEL"/>
AND	recommend	diet and exercise	<input type="button" value="AND"/>	<input type="button" value="OR"/>	<input type="button" value="DEL"/>

Check Executability

Executability

Is each recommended action(s) (what to do) stated specifically and unambiguously? That is, would members of the intended audience execute each action in a consistent way? If not, rewrite the action.

Recommended Action	
start	metformin as first-line treatment
recommend	diet and exercise

Add Conditions

When

Under what conditions will **start metformin as first-line treatment AND recommend diet and exercise** be performed?

Under What Conditions

newly diagnosed with type 2 diabetes

AND OR DEL

Check Decidability

Decidability

Would the guideline's intended audience consistently determine whether each condition has been satisfied? If not, rewrite the condition.

Condition

newly diagnosed with type 2 diabetes

Modify Condition to Clarify (if needed)

Decidable

Would the guideline's intended audience consistently determine whether each condition has been satisfied? If not, rewrite the condition.

Condition

newly diagnosed with type 2 diabetes, i.e., not previously treated

Describe Benefits

Benefits

What are the anticipated Benefits of
start metformin as first-line treatment AND recommend diet and
exercise

IF
newly diagnosed with type 2 diabetes, i.e., not previously treated

- Lower Hgb A1c
- Target A1c sustained longer
- Less early deterioration of blood glucose
- Lower chance of weight gain
- Improved insulin sensitivity
- Improved lipid profile

Risks, Harms, Costs

What are the anticipated Risks, Harms, and Costs of
 start metformin as first-line treatment AND recommend diet and
 exercise


IF
 newly diagnosed with type 2 diabetes, i.e., not previously treated

GI side effects
 Potential for lactic acidosis/B12 deficiency
 Cost of medication and administratiob
 SMBG
 Possible metabolic deterioration if Type 1 is misdiagnosed and
 treated as type 2
 Potential risk of lactic acidosis in setting of ketosis or significant
 dehydration

Judge Benefit-Harms Balance

Balance

Is there Equilibrium or a preponderance of Benefits or Risks, Harms, and Costs?



Benefits

Equilibrium

Preponderance of Risks, Harms, Costs

Preponderance of Benefit

Risks,
Harms,
Costs

Benefits

- Lower Hgb A1c
- Target A1c sustained longer
- Less early deterioration of blood glucose
- Lower chance of weight gain
- Improved insulin

SMBG

- Possible metabolic deterioration if Type 1 is misdiagnosed and treated as type 2
- Potential risk of lactic acidosis in setting of ketosis or significant dehydration

Select Aggregate Evidence Quality

Evidence Quality

What aggregate evidence quality supports these benefits, risks, harms, and costs?
start metformin as first-line treatment AND recommend diet and exercise

IF
newly diagnosed with type 2 diabetes, i.e., not previously treated

Evidence Quality

- A Well-designed, well-conducted randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population
- B Randomized, controlled trials with "nonfatal flaws" or methodologic limitations; overwhelmingly consistent evidence from observational studies
- C Observational studies (case control or cohort design)
- D Expert opinion, case reports, reasoning from first principles
- X Exceptional situations where validating studies cannot be performed and there is a clear preponderance of harm or benefit

Resumes

Quality Appraisal

Aggregate	RCT-Consort
RCT-Casp	Observation
MetaAnalysis	Diagnostic

Notes

Recommendation Strength

RULE EDITOR

Deontic

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well designed RCTs or diagnostic studies on relevant population	Strong	Option
B. RCTs or diagnostic studies with minor limitations;overwhelmingly consistent evidence from observational studies	Rec	
C. Observational studies (case-control and cohort design)	Option	No Rec
D. Expert opinion, case reports, reasoning from first principles	Rec	
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	Strong	

Based on the Quality of Evidence **Grade C** and **Preponderance of Benefit**
this key action statement can have a Recommendation Strength of **Recommendation**.

Based on this, the level of obligation should be **Should**

Define the “Actor”

Who

WHO is to start metformin as first-line treatment AND recommend diet and exercise IF newly diagnosed with type 2 diabetes, i.e., not previously treated?

Clinicians

Choose a Recommendation Style

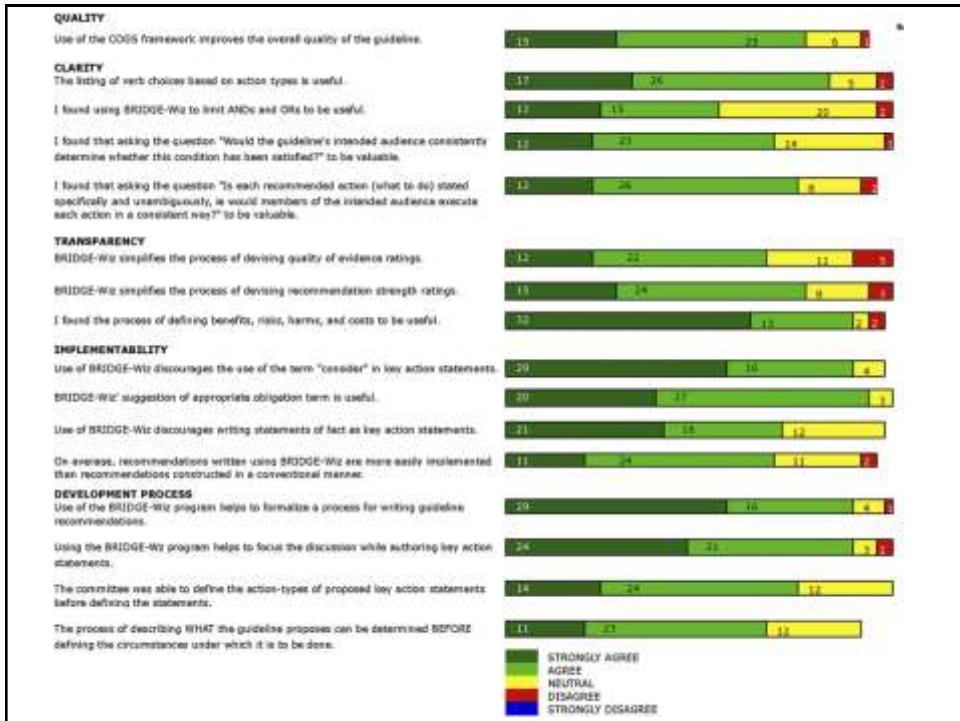
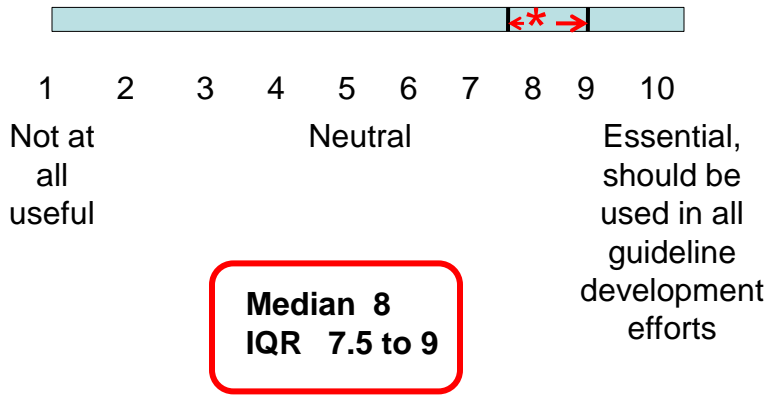
<p>If newly-diagnosed with type 2 diabetes (i.e., not previously treated) Then Clinicians should start metformin as first-line treatment AND recommend diet and exercise</p>	Select
<p>Clinicians should start metformin as first-line treatment AND recommend diet and exercise if/when/whenever newly-diagnosed with type 2 diabetes (i.e., not previously treated)</p>	Select
<p>The <i>{developer}</i> recommends that if newly-diagnosed with type 2 diabetes (i.e., not previously treated) Then Clinicians should start metformin as first-line treatment AND recommend diet and exercise</p>	Select
<p>The <i>{developer}</i> recommends that Clinicians should start metformin as first-line treatment AND recommend diet and exercise if/when/whenever newly-diagnosed with type 2 diabetes (i.e., not previously treated)</p>	Select

Evidence Profile Summary	
Date:	9/7/2009
Key Action Statement:	<p>Individuals diagnosed with type 2 diabetes (i.e., not primarily treated with insulin) should start metformin as first-line treatment. AND, recommend diet and exercise.</p>
Aggregate Evidence Quality:	Grade C
Benefit:	Lower HbA1c; longer duration of longer-term safety; decreases rates of blood glucose; lower chance of weight gain; improved insulin sensitivity; improved lipid profile
Risk, Harm, Cost:	Diarrhea; dizziness; lactic acidosis; B12 deficiency; cost of medication; cost to administer additional treatment; abuse of metformin; possible metabolic abnormalities if type 1 is not diagnosed; potential for lactic acidosis with kidney or significant dehydration
Benefit-Harm Assessment:	Preponderance of Benefit
Value Judgments:	
Intentional Vagueness:	
Role Of Patient Preferences:	
Exclusions:	

Evaluation

- Formally surveyed 50 developers (4 panels)
 - AAP: Acute otitis media
 - AAP: Sinusitis
 - AAP: Obstructive sleep apnea
 - AAO-HNS: Sudden hearing loss
 - AUA: Urodynamics

Overall Usefulness (N = 69)



BRIDGE-Wiz



Building Recommendations in a Developer's Guideline Editor

- Formalizes a process for writing implementable recommendations
- Focuses discussion
- Incorporates prompts based on COGS to improve guideline quality
- Controlled natural language
 - Offers verb choices based on action-type
 - Traps and disallows use of “consider”
 - Discourages “statement of fact” masquerading as recommendation
 - Limits boolean connectors to all ANDs or ORs in a statement
- Incorporates decidability and executability checks
- Requires systematic appraisal of evidence quality and benefit-harms
 - Suggests appropriate obligation term (deontic modal)
- Output includes a high-level “rule” and an evidence profile

Limitations

- Use of a regimented system for guideline development will be resisted by some guideline authors.
- BRIDGE-Wiz has only been tested at 3 professional organizations.
- Because BRIDGE-Wiz defines knowledge in a declarative manner, procedural details (as might be displayed best in a flowchart) are not well supported.



Thank you!

감사합니다

<http://gem.med.yale.edu/BRIDGE-Wiz>

Watch for our publication in: J Am Med Informatics Assoc